

### **Remarks**

Applicants have carefully reviewed the Office Action dated March 8, 2006. Claims 1-65 are pending. Claim 7 has been withdrawn. Claims 1-6 and 8-57 have been rejected and claims 1, 10, and 28 have been amended. Support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added. Reconsideration and reexamination are respectfully requested.

### **Double Patenting**

Claims 1-6, 8-28, and 37-65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,652,505. Claims 1-6, 8-28, and 37-65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,142,987. 6,652,505 is a continuation of 6,142,987, thus the rejections are addressed together.

Applicants submit that independent claims 1 and 10, as now amended, are distinguished from 6,652,505 and 6,142,987. Independent claims 25 and 37 recite, in part, an elongate tubular member having a lumen, a proximal end and a distal end, a first opening from the lumen at the distal end, and first and second outlet pathways from the lumen having first and second exits, respectively, where the first exit is proximal the first opening and the second exit is proximal the first exit and distal of the proximal end of the sheath. Neither 6,652,505 nor 6,142,987 appears to teach or suggest such a device. 6,652,505 and 6,142,987 appear to teach a device having distal and proximal ends and an opening 61 proximal of the distal end. See Fig. 11. 6,652,505 and 6,142,987 do not appear to teach a device having a second exit proximal a first exit and distal of the proximal end of the sheath, as is recited in independent claims 25 and 37. Additionally, there is no motivation for one of ordinary skill in the art to modify the device and method of 6,652,505 or 6,142,987 to achieve the device and method of the instant claims. Reconsideration and withdrawal of the rejections are respectfully requested.

### 35 U.S.C. § 102 Rejections

Claims 1-6, 8-28, and 37-65 are rejected under 35 U.S.C. § 102(e) as being anticipated by Tsugita (U.S. 6,142,987). Applicants respectfully traverse the rejection. In order for a reference to anticipate a claim, each and every element of the claim must be present in the reference. See M.P.E.P. §2131. Applicants assert that Tsugita does not disclose each and every element of the claimed invention. Independent claims 1 and 10, as amended, recite in part:

elongate tubular member having a first opening from the lumen at the distal end, [[and]] a second opening from the lumen proximal to the distal end, and a third opening from the lumen distal of the proximal end of the tubular member, the openings defining points at which the lumen opens to an environment surrounding the sheath;

(Emphasis added). Applicants submit that Tsugita does not appear to teach such an element. Tsugita teaches a support wire 10 inserted in lumen 51 of rapid exchange catheter 50 having skive 61 that receives guidewire 30. See Fig. 1I. Tsugita does not appear to teach an elongate tubular member having first, second and third openings from the lumen, where the third opening is distal of the proximal end. Additionally, there is no motivation, suggestion, or guidance for one of ordinary skill in the art to modify the device of Tsugita to achieve the instantly claimed device or method. Tsugita thus does not teach or suggest each and every element of independent claims 1 and 10, as now amended. Dependent claims 2-6, 8, 9, 11-24, 58, 59 recite additional elements not found in Tsugita. For at least the reasons set forth above, the claims dependent on independent claims 1 and 10 are also believed to be distinguished from Tsugita.

Independent claims 25 and 37 recite, in part, an elongate tubular member having a lumen, a proximal end and a distal end, a first opening from the lumen at the distal end, and first and second outlet pathways from the lumen having first and second exits, respectively, where the first exit is proximal the first opening and the second exit is proximal the first exit and distal of the proximal end of the sheath. Tsugita does not appear to teach or suggest such a device. Tsugita appears to teach a device having distal and proximal ends and an opening 61 proximal of the distal end. See Fig. 1I. Tsugita does not appear to teach a device having a second exit proximal a first exit and distal of the proximal end of the sheath, as is recited in independent claims 25 and 37.

Additionally, there is no motivation for one of ordinary skill in the art to modify the device and method of Tsugita to achieve the device and method of the instant claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-6, 8-28, and 37-65 are rejected under 35 U.S.C. § 102(e) as being anticipated by Boyle et al. (U.S. 6,537,294). Applicants respectfully traverse the rejection. In order for a reference to anticipate a claim, each and every element of the claim must be present in the reference. See M.P.E.P. §2131. Applicants assert that Boyle does not disclose each and every element of the claimed invention.

Independent claims 1 and 10, as amended, recite in part:

elongate tubular member having a first opening from the lumen at the distal end, [[and]] a second opening from the lumen proximal to the distal end, and a third opening from the lumen distal of the proximal end of the tubular member, the openings defining points at which the lumen opens to an environment surrounding the sheath;

(Emphasis added). Boyle does not appear to teach such a device. Boyle discloses a delivery system for embolic filter devices. As shown in Figures 7 and 8, the delivery system apparently comprises a delivery sheath 60 having a distal opening (right end), a guidewire lumen 62 having a proximal opening, and a filter lumen 64 having a proximal opening (left end). Even if one were to consider the guidewire lumen 62 and filter lumen 64 as a single lumen as asserted by the Examiner, Boyle does not teach a second opening from the lumen proximal to the distal end and a third opening from the lumen distal of the proximal end of the tubular member, where the openings define points at which the lumen opens to an environment surrounding the sheath, as is now recited in independent claims 1 and 10.

The Examiner provides a diagram illustrating the asserted first, second, and third openings in the device of Boyle. The claims recite the openings defining points at which the lumen opens to an environment surrounding the sheath. Applicants submit that the third opening asserted by the Examiner is the junction between lumens 62 and 64, and is not open to the environment surrounding the sheath. At best, Boyle appears to teach a sheath having a distal opening, a proximal opening and a single additional opening; what the Examiner asserts is the second opening. Boyle does not teach each and every element of independent claims 1 and 10, as not amended. Dependent claims 2-6, 8, 9, and 11-24

recite additional patentably distinct elements. For at least similar reasons, Boyle does not teach or suggest the additional elements recited in the claims dependent on claims 1 and 10.

Further, Boyle does not disclose each and every element of independent claims 25 and 37. Claims 25 and 37 recite, in part, a sheath comprising an elongate tubular member having a lumen, a first opening from the lumen at a distal end of the tubular member, and first and second outlet pathways having first and second exits, respectively. The exits define the point at which the first and second pathways open to an environment surrounding the sheath. The first exit is proximal the distal end and the second exit is proximal the first exit and distal of the proximal end of the sheath. Boyle is missing at least this configuration of openings, outlet pathways and exits.

Referring to the labeled drawing of Boyle provide by the Examiner in the Office Action, the "first opening" appears to be at the distal end, however, if one considers the "second opening" to be a first exit, Boyle does not teach a second exit proximal the first exit and distal of the proximal end of the sheath, as is recited in the claims. The claims recite the first and second exits as defining points at which the first and second outlet pathways open to an environment surrounding the sheath. The portion of the device of Boyle asserted by the Examiner to be the "third opening" does not appear to be open to an environment surrounding the sheath and thus cannot be considered to be an "exit" as recited in the claims.

Boyle does not appear to have a lumen that has a first opening along with first and second exits as described in claim 25. Specifically, no lumen in Boyle has a first opening at the distal end of the sheath along with a first exit proximal of the distal end and a second exit proximal of the first exit and distal of the proximal end of the sheath. (Again, the exits of claim 1 define the points at which the first and second outlet pathways open to an environment surrounding the sheath.) Because Boyle does not disclose at least this portion of claim 25, Applicants assert that claim 25 is patentable over Boyle. Further, because claim 37 contains similar language, claim 37 is also allowable. Because they are dependent on claims 25 and 37 and because they contain additional patentably distinct elements, Applicants respectfully assert that claims 26-28, 38-57, and 60-65 are also patentable over Boyle.

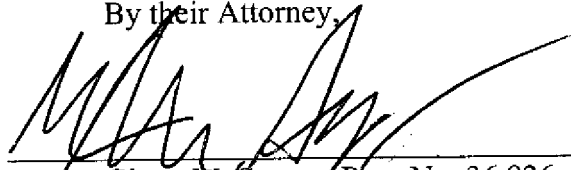
Reexamination and reconsideration are respectfully requested. It is submitted that all pending claims are currently in condition for allowance. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at 612-677-9050.

Respectfully submitted,

W. MARTIN BELEF ET AL.

By their Attorney,

Date: July 5, 2006

  
\_\_\_\_\_  
Glenn M. Seager, Reg. No. 36,926  
CROMPTON, SEAGER & TUFTE, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, Minnesota 55403-2420  
Tel: (612) 677-9050